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September 25, 2017

VIA ECF

Hon. Paul A. Crotty
United States District Court
Southern District of New York
500 Pearl Street, Courtroom 14C
New York, NY 10007

Re: *In re Insys Therapeutics, Inc., Shareholders' Litigation*, No. 17-cv-1954-PAC

Dear Judge Crotty:

Pursuant to Your Honor's Individual Rules, Lead Plaintiff Michael Robson ("Plaintiff") respectfully submits this letter in response to the Defendants' September 20, 2017 letter regarding their anticipated motion to dismiss the Amended Class Action Complaint ("CAC").¹

BACKGROUND:

Defendant Insys Therapeutics, Inc. ("Insys"), is a pharmaceutical company that produces pain management medicines. ¶2. Insys's only marketed product is Subsys, which was approved by the FDA in January 2012 *only* as treatment for breakthrough cancer pain and which could only be reimbursed by third-party payers for such purpose. ¶¶2, 34. By Defendants' own admission Insys' profitability as a corporation was dependent on the commercial success of Subsys. ¶30. Insys offered customers a full refund for returns of Subsys, as well as rebates to third-party payers to offset the cost of Subsys. ¶¶35, 49.

This securities fraud class action concerns Defendants' fraudulent concealment of Insys's declining revenues from Subsys in the face of intense regulatory scrutiny and the withdrawal of its primary customers – third party payers. ¶1. From the inception of its existence through 2015,

¹ References to "¶ __" are to paragraphs in Plaintiff's CAC.

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Defendants perpetrated an illegal kickback scheme to induce third-party payers into prescribing Subsys for uses other than breakthrough cancer pain. ¶¶40-41. As a result of increased regulatory scrutiny, third-party payers began to deny Insys's coverage requests² which led to increased returns of (and refunds for) Subsys after Insys had already issued rebates on the returned product. ¶¶ 43, 51. Accordingly, throughout the class period Defendants perpetrated a scheme to overstate revenue by understating the company's sales allowance relating to its returns and rebates in violation of its own internal accounting policies and GAAP, and, in the process, reporting a myriad of false statements. ¶248. On March 31, 2017, Insys announced that its financial statements for the quarters ended September 30, June 30, and March 31, 2016 and 2015, should no longer be relied upon because of errors related its accounting of its sales allowances. ¶212. Defendants expressly acknowledged, that the impact of these errors was "*material*," and were the result of an inadequate "*tone at the top*" amongst management. *Id.* Upon this news, the price of Insys common stock declined from a closing share price of \$11.04 per share on March 29, 2017 to close at \$10.51 on March 31, 2017, a loss of 5%, on heavy trading volume. ¶6.

DEFENDANTS' GROUNDS FOR THEIR MOTION TO DISMISS ARE MERITLESS:

Defendants' first and second purported grounds for dismissal assert that the CAC fails to sufficiently plead why Defendants' statements were false or misleading "at the time they were made." *See* Defendants' September 20, 2017 Letter at 2.³ Defendants fail to acknowledge that "the mere fact that financial results were restated is sufficient basis for pleading that those statements were false when made." *S.E.C. v. Espuelas*, 908 F. Supp. 2d 402, 410 n.5 (S.D.N.Y. 2012). Under GAAP, "previously issued financial statements should be restated *only to correct*

² Defendants repeatedly acknowledged coverage issues. *See* ¶¶ 43, 156.

³ Defendants' first ground asserts that the statements were insufficiently plead, whereas the second ground asserts the statements were puffery, forward-looking, expressions of opinion, or otherwise nonactionable. Because the statements were false and misleading at the time they were made, this is a distinction without a difference.

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material accounting errors that existed at the time the statements were originally issued.” *In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 486 (S.D.N.Y. 2004) (citations omitted) (emphasis added). Therefore, “[m]isreported financial information clearly amounts to a false statement of fact.” *Varghese v. China Shenghuo Pharm. Holdings, Inc.*, 672 F. Supp. 2d 596, 606 (S.D.N.Y. 2009); *see also* 17 C.F.R. § 210.4-01(a)(1) (“Financial statements filed with the Commission which are not prepared in accordance with generally accepted accounting principles will be presumed to be misleading or inaccurate, despite footnote or other disclosures.”). The CAC unequivocally states which financial statements were misstated and how they affected Insys’s stock price. Moreover, Defendants themselves admit that the misstatements were “material.” Consequently, Defendants’ arguments fail.

Lastly, Defendants assert that the CAC fails to adequately allege scienter. A complaint sufficiently establishes scienter when, “a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S., 308, 324 (2007). Here, Plaintiff alleges Defendants acted knowingly or recklessly because, *inter alia*: (1) Defendants’ admitted their false statements were the product of an inadequate “tone at the top;”⁴ (2) they monitored Subsys prescriptions “in real-time” every day; (3) they were admittedly in constant communication with third-party payers; (4) they violated their own accounting policies and GAAP; (5) the viability of Subsys was Insys’s “core” business; (6) insiders’ conveniently timed stock sales; and (7) the curiously timed departures of Insys’s entire management team. This is sufficient to allege scienter.

⁴ *See Fresno Cty. Emples. Ret. Ass’n v. comScore, Inc.*, 2017 U.S. Dist. LEXIS 119648 at *50-*51 (S.D.N.Y. July 28, 2017) (defendants’ admitted “concerns about tone at the top” were found to be probative of scienter because “[u]nlike cases in which misrepresentations plausibly result from issues flowing from the bottom-up (for example, where subordinates fail to give executives pertinent information), it is more plausible based on the disclosure that the fraud flowed from the top-down.”).

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We are happy to answer any additional questions at the pre-motion conference.

Respectfully submitted,

/s/ Shannon L. Hopkins
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